K081385

OCT 09 2008

Revised 510(k) Summary

Manufacturer Name:	EastMed Inc.
Contact Name:	Karen Farrell
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Email:	kfarrell@eastmed.ca
Date Prepared:	September 22, 2008
Proprietary Name:	uresta™ Pessary
Common/Usual Name:	Vaginal Pessary
Classification Name:	Pessary, Vaginal
Classification Code:	HHW

Predicate Devices

Substantial equivalence is claimed to the following devices as related to intended use, mechanism of action and design characteristics:

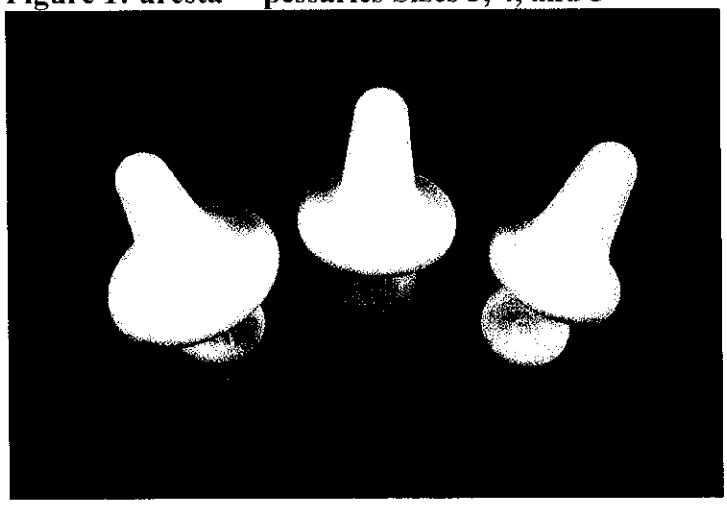
- Milex Incontinence Ring, Flexible Pessary, Cooper Surgical
- Milex Incontinence Ring with Knob and Support, Cooper Surgical
- Introl Bladder Neck Support Prosthesis, Johnson & Johnson (K930618, K965040)
- PelvX Incontinence Dish, Deschutes Medical Products Inc. (K990593)

Description of the Device

The uresta™ Pessary is designed for adult women who experience involuntary urine loss from the most common type of incontinence; stress incontinence, from physical activity such as coughing, laughing and/or exercising.

uresta™ Pessary is a bell-shaped vaginal pessary with a handle at its base for easy insertion and removal (Figure 1).

Figure 1: uresta™ pessaries Sizes 3, 4, and 5



uresta™ Pessary stops leaking from the bladder by supporting the urethra. The narrow tip allows for easy insertion into the vaginal introitus. It is inserted directly into the vagina like a tampon and seats itself so that the wide base provides support to the urethra. It is made of medical grade injection moulded Santoprene (non-latex thermoplastic rubber).

uresta™ Pessary is available individually in sizes1 (30 mm), 2 (34 mm), 3 (38 mm), 4 (43 mm), 5 (48 mm), 6 (52 mm) or 7 (56 mm). The products are sold individually, and as a kit including one each of sizes 3, 4, 5, the most commonly used sizes. After initial fitting, a patient may request to try a different size for maximum benefit. All sizes are available to accommodate patients requiring larger or smaller than average sizes, and for periodic replacements.

For proper use (insertion/removal techniques) and maintenance see package insert.

Intended Use of the Device

This device is for the use in adult women, over 18 years of age who experience involuntary urine loss with physical activity (stress urinary incontinence).

Technological Characteristics

The uresta™ Pessary and the predicate devices alleviate stress incontinence by pressure through the anterior vaginal wall onto the urethra.

Conclusion

The uresta™ Pessary is substantially equivalent to the predicate devices in term of functional design, indications of use and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

EastMed, Inc.
c/o Shirley Furesz, Ph.D.
Senior Regulatory Affairs Associate
CanReg Inc.
4 Innovation Drive
DUNDAS ON L9H 7P3
CANADA

Re: K081385
Trade Name: Uresta™ Pessary
Regulation Number: 21 CFR §884.3575
Regulation Name: Vaginal pessary
Regulatory Class: II
Product Code: HHW
Dated: September 29, 2008
Received: September 30, 2008

Dear Dr. Furesz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 081385

Device Name: uresta™ Pessary

Indications for Use:

This device is for the use in adult women, over 18 years of age who experience involuntary urine loss with physical activity (stress urinary incontinence).

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081385